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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,967	10/15/2004	Carl Sidonius Maria Andela	12810-00749	3397

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EXAMINER
NOAKES, SUZANNE MARIE

ART UNIT	PAPER NUMBER
1656	

MAIL DATE	DELIVERY MODE
12/23/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/500,967	Applicant(s) ANDELA ET AL.	
	Examiner SUZANNE M. NOAKES	Art Unit 1656	

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-55 is/are pending in the application.
- 4a) Of the above claim(s) 53-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>30 October 2008</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The Examiner and Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656 and the Examiner signed below.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 October 2008 has been entered.

Status of the Application

3. The amendments to the claims and remarks filed 30 October 2008 are acknowledged. Claims 33-53 are pending, claims 53-55 remain withdrawn as they are directed to non-elected subject matter and claims 33-52 are subject to examination on the merits.

Withdrawal of Objections and Rejections

4. The rejections of: i) claims 33-34, 38-39, 41-42, 45-49 and 52 under 35 U.S.C. 102(b) as being anticipated by Dale et al., United States Patent No. 5,879,920; ii)

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claims 33-34, 38-39, 42, 44-50 and 52 rejected under 35 U.S.C. 102(e) as being anticipated by De Lima et al. United States Patent No. 6,589,929; and iii) Claims 35-37, 40 and 43 rejected under 35 U.S.C. 103(a) as being unpatentable over Dalè et al. United States Patent No. 5,879,920 in view of Masschelein et al. United States Patent No. 6,103,678 - are all hereby withdrawn in view of Applicants arguments. Polyethylene glycol is not a polyolefin and thus the prior art of record does not teach the limitations of the instant claims.

New Objection(s) and Rejection(s)

Claim Rejections - 35 USC § 112 – 1st paragraph

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 35-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the claims encompass a polyolefin dispersion containing acidic groups which are stabilized by an amine, wherein the acidic group are carboxylic groups and the amine is ammonia. The specification provides an adequate written description of polyolefins in general. However, the description of the compounds encompassed by claims 35-37, which are deemed as

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derivatives of polyolefins, is scant/minimal and no examples of such polymers are provided. The specification fails to describe the disposition of the acidic groups in the polymer (e.g. in the chain or as pendant groups) or what the nature of the stabilization is. For instance, it is not clear if the amine ammonia is intended to be a salt or not. Thus, the polymers encompassed by claims 35-37 are vaguely described and the specification as filed clearly does not provide a representative number of species of the polymers encompassed by the claims, given the huge variation in physical, structural, and chemical properties encompassed by the current broad claim language. Therefore, because the claims encompass a multitude of polymers neither contemplated nor disclosed by the as-filed disclosure, it is clear that applicant was not in possession of the full scope of the claimed subject matter at the time of filing.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 33, 35, 36, 38, 42, 45 and 52 rejected under 35 U.S.C. 102(b) as being anticipated by Itoh et al. (US 5,080,917; cited in the IDS filed 10/30/2008).

Itoh et al. teach coated granules for animal feed and a method of making said granules. The core can comprise a starch and an active substance that can be an enzyme such as a protease (col. 2, lines 44-50), as in claims 1 and 38. Other

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constituents include amino acids and vitamins. The enzyme-core granulate is prepared by conventional means which include granulating, drying and making the granule in a spherical shape (col. 4, lines 15-55). The coating agent comprises copolymers formed from alkyl esters of methacrylic acid and dimethylaminoethyl methacrylate such as Eudragit E100 (Butyl methacrylate-2-(dimethylamino)ethyl methacrylate-methyl methacrylate polymer). Said compound broadly but reasonably interpreted is interpreted as a polyolefin which is derivatized by adding a pendant chain to a polyolefin having a carboxy group which is made into a salt by the presence of a quaternary amine.

It should be noted, that in effect, the limitations of claim 35-37 are interpreted to mean a polymer of (meth)acrylic acid ammonium salt. The disclosure by Itoh et al. meets these limitations, because Eudragit contains methacrylate monomers and polymers that are interpreted to meet the limitation of claims 33, 35 and 36 for the reasons stated. Itoh et al. disclose that these polymeric coatings are water soluble and can be applied by a spraying method as an aqueous solution to the granules (col. 4, lines 55-64). The polymer coating can be applied to the granule individually or with an additive such as ethyl cellulose (col. 3, lines 35-40). It is noted that the language of the instant claims is open and that the claimed coatings can comprise other substances. The ratio of the coating to the granule core is at a weight ratio of 5 parts per 100 parts core (col. 4, lines 30-40). Thus, in a coated granule, the percent weight ratio is about 2.5 to 50%, which overlaps the range of claim 45.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Itoh et al. as applied to claims 33, 35, 36, 38, 42, 45 and 52 above and in view of Thoma et al. (1999) – cited on IDS from 10/30/2008.

The teachings of Itoh et al. are described above.

Itoh et al., however, do not teach that the polyolefin derivative is a (meth)acrylate that is stabilized by an ammonia.

Thoma et al. disclose a comparison of the stability of a range of enteric polymer coatings on enzyme-containing granules and tablets containing vitamin B12. The polymers included an aqueous dispersion of methacrylic/acrylate copolymers (Eudragit

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L 100-155 and Eudragit L 30D55) with and without ammonia. Thoma et al. report that the Eudragit polymers were coated onto the pills containing B12. The Eudragit polymers maintained their stability and gastrointestinal protective ability after long term storage under various conditions of temperature and humidity. A coating comprising the Eudragit polymers with ammonia had the same effect as a coating having a Eudragit polymer lacking ammonia (Figure 1, page 41).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ Eudragit polymers with or without ammonia as a coating for the enzyme-containing granulates of Itoh. The ordinary artisan would have been motivated to do so because the purpose of the coatings of Itoh and Thoma is the same: to protect the biologically active substance from the environment while in storage and the gastrointestinal acid of the stomach on first pass. The ordinary artisan would have realized that methacrylic co-polymers such as Eudragit polymers are effective at accomplishing both aims. The ordinary artisan would have realized from Thoma that the addition of ammonia is a matter of design choice as it does not have a deleterious effect on the stability of the Eudragit polymers.

Double Patenting

11. Claims 33-52 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4-8, 12-18 and 20-26 of copending Application No. 10500144. Although the conflicting claims are not identical, they are not patentably distinct from each other because the process of

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making the product as claimed in the co-pending application would be an obvious method to make the instantly claimed products.

The co-pending application claims methods of making coated granulates comprising a dry enzyme wherein said granulate is coated with a polyolefin selected from polyethylene, polybutylene, polypropylene and/or polybutadiene (see claim 1) and an enzyme-coated granulate coated with a polyolefin prepared wherein said granulate is prepared by said process of claim 1 (see claim 13). These same polyolefins of claim 1 are preferred embodiments of the instant application and are also claimed in the instant claim 39. The claimed process describes the necessary steps one skilled in the art would use to make the instantly claimed products having the requisite limitations such as desired melting temperature (instant claim 41, and co-pending claim 4), etc. Thus, the difference in scope of the claimed inventions is limited the product versus the process, however, as noted, it would be obvious to use the co-pending product to make the instantly claimed products.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

12. No claims are allowed

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUZANNE M. NOAKES, Ph.D. whose telephone number is (571)272-2924. The examiner can normally be reached on 7.00 AM-3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SUZANNE M. NOAKES/
Primary Examiner, Art Unit 1656
03 December 2008